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| 10/727,096 | 12/02/2003 | David K. Swanson | 03-0242 (US01) | 6001 |
| 41696 7590 11/09/2007 VISTA IP LAW GROUP LLP 12930 Saratoga Avenue Suite D-2 Saratoga, CA 95070 | | | EXAMINER ROANE, AARON F | |
| | | | ART UNIT 3739 | PAPER NUMBER |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/727,096

Applicant(s)

SWANSON, DAVID K.

Examiner

Aaron Roane

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 August 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 7,8,10-12,28-35,37-40,43,44,46,47 and 54-56 is/are pending in the application.
- 4a) Of the above claim(s) 12 and 29 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 7,8,10,11,28,30-35,37-40,43,44,46,47 and 54-56 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 02 December 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application
- ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 7, 8, 10, 11, 28, 30, 40, 43, 44, 46, 47 and 54-56 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lundback (US 4,736,749) in view of Samson (US 6,185,442).

Regarding claims 7, 8, 10, 11, 28, 43, 44, 46 and 47, Lundback discloses a surgical apparatus comprising a tube (8) defining an axis (inherent) and having a proximal region (with a proximal end) and a distal region (with a distal end); a cup-shaped suction device (1-3 collectively) associated with the distal region of the tube and defining a surface (surface defined by 4), wherein the cup-shaped suction device is made from a flexible material (flexible bending portions of 2), a tissue stimulation electrode (the tissue contacting side of 30) on the suction device distal surface; a source of stimulation energy ("electrical power source not shown" see col. 3, lines 3-12) connected to the stimulation electrode; and a suction source (see col. 3, lines 26-29), see col. 3 and 4 and figures 1-4.

It should be further noted the width of the distal surface (4) is greater than a width of the distal end of the tube (diameter of 3), see figures 1-3. Finally, Lundback discloses a signal line (7) connected to the tissue stimulation element and extends through the tube, see figures 1-3 and col. 1-2. Lundback fails to disclose a distal surface that has normal vector (a direction traverse and away from the surface) that is aligned with the central longitudinal axis of the tube. Lundback also fails to disclose a flexible suction tube. Samson discloses a suction electrode device comprising a suction device (10), a tube (15) and an electrode (16) and teaches the use of connecting the suction cup (10) to the pressure manipulator (14) via a bendable hose/tubing (15) in order to provide suction or vacuum pressure to the cup and to facilitate the comfort and versatile positioning during use and further teaches an alternative arrangement of the suction device (10) and tube (15) such that the normal vector of the suction device is aligned with the central axis of the tube, see col. 3 and 4 and figures 1-3. This combination provides a suction device connected to the distal end of a tube wherein the distal surface of the suction device has a normal vector that is aligned with the central axis of the tube, i.e. the suction device and tube have coaxial central axis. Therefore at the time of the invention it would have been obvious to one of ordinary skill in the art to modify the invention of Lundback, as taught by Samson, to use a bendable hose/tubing in order to connect the suction cup to the pressure manipulator and to facilitate comfort and versatile positioning during use, and as further taught by Samson, to provide the alternate arrangement of the suction device and tube as a means of providing suction and electrical energy delivery to tissue.

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Regarding claims 30 and 40, Lundback discloses an electrode size for the stimulation electrode that does not form a lesion of any kind at all, see col. 3 and 4 and figures 1-4.

Regarding claims 54-56, Lundback in view of Samson disclose the suction device that defines lumen (small, shallow opening which connects the tube to the suction device), the suction device is connected to the suction source by the lumen, and the distal surface carrying the tissue stimulation element extends outwardly beyond lumen.

Claims 31-33 and 37-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lundback (US 4,736,749) in view of Samson (US 6,185,442) as applied to claims 7 and 28 above, and further in view of Rau (US 4,685,466).

Regarding claims 31-33 and 37-39, Lundback in view of Samson disclose the claimed invention except for explicitly reciting that the stimulation electrode defines a perimeter of about 1.5 mm to 3mm, a thickness of about 0.01 mm and/or a diameter of about 0.5 mm to 1.0 mm. Rau discloses a stimulation suction electrode and teaches providing the electrode in a needle configuration (1) in order to provide fixation without electrode paste or jelly and to reduce skin resistance, see col. 3, lines 1-15, col. 4, lines 29-49 and figures 4-6. The needle electrode of Rau provides all of the recited dimensions of the claimed invention. Therefore at the time of the invention it would have been obvious to one of ordinary skill in the art to modify the invention of Lundback in view of Samson, at taught

by Rau, to provide the suction electrode with a needle electrode in order to provide fixation without electrode paste or jelly and to reduce skin resistance.

Claims 34 and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lundback (US 4,736,749) in view of Samson (US 6,185,442) as applied to claim 28 above, and further in view of Colliou et al. (US 7,020,531).

Regarding claims 34 and 35, Lundback in view of Samson disclose the claimed invention except for explicitly reciting that the source of stimulation is configured to provide stimulation pulses that are about 1 msec in duration, 10 mA and two stimulation pulses per second. Colliou et al. disclose a stimulating suction electrode device and teach providing the device with a power source capable of delivering 1 mA to 30 mA of current, a pulse width of 0.1 msec to 500 msec and a pulse burst repetition period of about 100 μ sec to 20 msec in order to provide electrical stimulation, see col. 23, line 46 through col. 24, line 6 and figures 16A and 16B. Therefore at the time of the invention it would have been obvious to one of ordinary skill in the art to modify the invention of Lundback in view of Samson, as taught by Colliou et al., to provide the device with a power source capable of delivering 1 mA to 30 mA of current, a pulse width of 0.1 msec to 500 msec and a pulse burst repetition period of about 100 μ sec to 20 msec in order to provide electrical stimulation to tissue.

Response to Arguments

Applicant's arguments filed 8/20/2007 have been fully considered but they are not persuasive. The examiner will address each argument/remark in turn.

Regarding Applicants remarks in response to the "objected to" subject matter of "the suction device being removably securable to myocardial tissue," the examiner can not figure out why that was included in the response to arguments section of the office action filed 5/14/2007 and can only conclude that it was inadvertently included. However the examiner's statement of intended use was and still is valid as Applicant has now recited "the suction device having a shape and a size for being removably securable to myocardial tissue." The reason is quite simple, the prior art suction device has a size and shape, both inherent. That intended use comes about due to the fact that the suction device is used to be secured (removably) to myocardial tissue which the prior art of record is clearly capable of doing. Again, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. Applicant has presently attempted to get around the intended use matter by reciting that the suction device has a size and shape, which any and all physical matter has and therefore is incredibly broad.

Next we turn to Applicant's arguments/remarks against the rejections made under 35 U.S.C. 103(a) as being unpatentable over Lundback (US 4,736,749) in view of Samson (US 6,185,442).

On page 8, second paragraph Applicant requests clarification. First, Applicant's interpretation and conclusion that

it is also conceded that Lundback fails to disclose, teach or suggest the structural configuration of a tube defining an axis and a suction device "connected to and coaxial with the distal end of the tube and having a distal surface, a width of the distal surface being greater than a width of the distal end of the tube" as recited in claims 1, 28 and 43,

is incorrect. What was (and is) conceded is that Lundback fails to disclose a distal surface that has normal vector (a direction traverse and away from the surface) that is aligned with the central longitudinal axis of the tube. In other words, the central axis of the tube and the central axis of the suction device (the axis that passes through the centers of 1, 2 and 3 and defines the direction of motion by which 1, 2 and 3 movably engaged) are not coaxial. It should be noted Applicant is not strictly reciting that the central axis of the tube and suction device are coaxial. Applicant is only reciting some undefined axis of the tube and another undefined axis of the suction device are coaxial, which are disclosed by Lundback as the axis are undefined.

This whole discussion is moot as the examiner has provided a secondary reference that clearly teaches providing a suction cup and tubing that are clearly coaxial with respect to their central axis.

Regarding Applicant's assertion (see third paragraph on page 8) that Lundback fails to disclose a suction device that is made/formed from a flexible material, the examiner strongly disagrees. Indeed sealing lip 13 is disclosed as being rigid. However it is very clear from figures 2 and 3 that 2 has flexible portions. Additionally, Applicant admits on the record that portions of

2, namely flange 17 is elastic (flexible), see last paragraph on page 8, lines 5-8). In the previous action the flexible portion was incorrectly identified as 1 which was a typographical error.

On page 9, first full paragraph, Applicant asserts that Lundback does not disclose “the tissue stimulation element being supported on the suction device distal surface.” Again the examiner strongly disagrees as Lundback clearly discloses the electrode (4) comprising the distal surface of the suction device, see figures 1-3. Although operational characteristics of an apparatus may be apparent from the specification, we will not read such characteristics into the claims when they cannot be fairly connected to the structure recited in the claims. See *In re Self*, 671 F.2d 1344, 1348, 213 USPQ 1, 5 (CCPA 1982).

Next, Applicant asserts (see page 9, third full paragraph) Lundback fails to disclose the suction device is “substantially cup-shaped.” The examiner disagrees as Lundback clearly discloses a that (2) is substantially cup shaped. Lundback discloses “parts 1 and 2 are rotationally symmetric” and has an annular/cylindrical wall (13) connected to a bottom (area adjacent 11, 12, 18 and 19), see col. 3, lines 38-44 and figure 1.

Regarding the Applicants arguments/remarks against the teachings of Samson, see page 9, second from last paragraph through page 10, second from last paragraph, Samson is used to teach providing a suction device with a flexible tube that is coaxially aligned, wherein the coaxial alignment is consistent with Applicant’s narrow interpretation. Applicant goes on to point out all of Samson’s failings with respect to filling in the supposed deficiencies of Lundback in this same said passage. However, these supposed deficiencies have been shown by the above response to arguments/remarks against Lundback to be limited only this coaxial relationship between the central axis of the tube and the suction device. Therefore the remaining

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arguments/remarks leveled by the Applicant against Samson boil down to arguing against the rejections based on Samson alone or individually. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Next Applicant asserts on page 11, second paragraph, that Rau does not disclose, teach or suggest all of the claimed electrode dimensions missing from Lundback and Samson. The examiner disagrees and points out that Rau discloses electrode needles that have cylindrical portions that are narrower than 0.5 mm and therefore the cone shaped portions inherently meet the claimed limitations, see col. 3, lines 53-68 and figures 1a-7.

Next Applicant refutes the combination of Lundback and Samson with Rau, see page 11, second to last paragraph. Applicant asserts "the basis for the reason for combining the references is not clear. If the rejection stands, Applicant respectfully requests the Examiner to identify the section of Lundback that describes use of paste or jelly and the reason for use of a needle electrode in Lundback." The rejection is very clear as to the rationale for combining, the examiner directs Applicant to the rejection in question. Additionally, the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. *In re Keller*, 642 F. 2d 413, 425, 208 USPQ 871, 881 (CCPA 1981). In this regard, a conclusion of obviousness may be based on

common knowledge and common sense of the person of ordinary skill in the art without any specific hint or suggestion in a particular reference. In *re* Bozek, 416 F.2d 1385, 1390, 163 USPQ 545, 549 (CCPA 1969).

In the last paragraph on page 11, Applicant also asserts “that a person of ordinary skill in the art would not combine the cited references given the particular and different structural configurations and functionality.” In response to applicant's argument that “that a person of ordinary skill in the art would not combine the cited references given the particular and different structural configurations and functionality,” the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981).

Regarding the remaining arguments with respect to the rejections based on the combination of Lundback, Samson and Rau (see page 12), Applicant as further argued against the references individually, and as pointed out before, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

On page 13, Applicant asserts (see second paragraph) Colliou does not disclose, imply, suggest and/or teach a “source of stimulation is configured to provide stimulation pulses that are about 1 msec in duration, 10mA and two stimulation pulses per second.” In the cited passage,

Colliou discloses pulse widths (duration) of about 0.1 to 500 msec, currents of about 1 to 30 mA, and pulse repetition rate of about 100 μ s to 20 ms, see col. 23, line 46 through col. 24, line 6.

This meets the claimed limitations.

Next in the second to last paragraph on page 13, Applicant refutes the combination stating that “a person of ordinary skill in the art would not combine the cited references since they describe devices having different structural configurations for different purposes.” First, in response to applicant's argument that “different structural configurations”, the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981). Secondly, regarding the “different purposes,” the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. In *re Keller*, 642 F. 2d 413, 425, 208 USPQ 871, 881 (CCPA 1981). In this regard, a conclusion of obviousness may be based on common knowledge and common sense of the person of ordinary skill in the art without any specific hint or suggestion in a particular reference. In *re Bozek*, 416 F .2d 1385, 1390, 163 USPQ 545, 549 (CCPA 1969).

This action is made FINAL.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Aaron Roane whose telephone number is (571) 272-4771. The examiner can normally be reached on Monday-Thursday 7AM-6PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Aaron Roane *A.R.*
November 1, 2007

/Michael Peffley/
Primary Examiner
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